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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,787	09/12/2003	David W. Pascual	MONT-047/02	7809

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,787	PASCUAL, DAVID W.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 27-36, and 55-63, drawn to a composition comprising an M cell specific ligand, a nucleic acid encoding an immunogen, and a nucleic acid binding moiety, and methods of using said composition as a vaccine to immunize a host, classified in classes 435 and 514, subclasses 320.1 and 44 respectively.

II. Claims 12-16, 23-26, and 64, drawn to a composition comprising an M cell specific ligand, an immunogen and a linker molecule, classified in class 530 and 424, subclasses 350 and 184.1 respectively.

III. Claims 17-19, and 64, drawn to a composition comprising an M cell specific ligand, an immunogen, and a liposome, classified in classes 530 and 424, subclasses 350, and 184.1 or 450.

IV. Claims 20-22, and 64, drawn to a composition comprising an M cell specific ligand, an immunogen, and a polypeptide, classified in classes 530 and 424, subclasses 350 and 184.1 respectively.

V. Claims 37-39, drawn to methods of assaying for mucosal immunity comprising administering a vaccine, isolating mucosal immune cells and co-incubating the isolated cells with heterologous antigen presenting cells, classified in class 435, subclasses 347 and 373.

VI. Claims 40-45, and 47-49 drawn to an isolated nucleic acid encoding a fusion protein comprising a nucleic acid binding moiety and an M cell specific ligand,

vectors encoding said nucleic acids, hosts cells comprising the vector and method of producing the fusion protein, classified in classes 536 and 435, subclasses 23.1, and 320.1, 325, and 69.1 respectively.

VII. Claims 46, and 50-53, drawn to a fusion polypeptide comprising a nucleic acid binding moiety and an M cell specific ligand, classified in class 530, subclass .

VIII. Claim 54, drawn to an antibody that binds to a fusion polypeptide, classified in class 530, subclass 387.1

IX. Claims 55-63, drawn to a kit comprising an M cell specific ligand and an immunogen binding moiety, classified in class 530, subclass 350.

Claim 64 link(s) inventions II-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 64. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and Inventions II-IV are patentably distinct in that the composition of invention I includes a nucleic acid molecule encoding an immunogen and a nucleic acid binding moiety which are not required for the compositions of inventions II-IV and are structurally, materially, and functionally different from the immunogens, linker molecules, liposomes, and polypeptides in the compositions of claims II-IV. As such, the search and examination of each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions I-IV together.

2) Inventions II-IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while the compositions of each invention share an M cell specific ligand and an immunogen, each combination further includes a distinct element. These distinct elements, a liposome, a linker, and a polypeptide, do not overlap in scope and are not obvious variants. In addition, the compositions have different modes of operation and function based on these distinct elements. It is further noted that the subcombination of the M cell specific ligand and the immunogen have utility in more than one combination as evidenced by claims 12,

17, and 20. Therefore, in view of the distinct and structurally different elements present in inventions II-IV, the search for each of these inventions is not co-extensive and it would place and undue burden on the examiner to search and examiner all of these inventions together.

3) Invention I and Invention V are related as product and process of use. The inventions can be shown to be distinct if **either** or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the vaccine used in the methods of invention V can be used in methods other than methods of assaying for mucosal immunity, such as the use of the vaccine to immunize a mammal or to transfect an antigen presenting cell *in vitro*.

4) Inventions II-IV and V unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of invention V do not utilize and do not require the compositions of inventions II-IV. Further, the compositions of inventions II-IV have different structural features and modes of operation than the vaccines used in the methods of invention IV. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of these inventions together.

5) Invention VI is unrelated to all of inventions I-V and VIII-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acids, vectors and cells of invention VI are not a part of any of the compositions of

inventions I-IV or VIII-IX as claimed and are further substantially different in structure and function from the elements comprised in these compositions. As such, the search for each is not co-extensive and it would place an undue burden on the examiner to search and examine all of these inventions together

6) Inventions VI and VII are related in part as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the fusion protein of invention VII can be made using a different process than that of invention VI which utilizes a nucleic acid encoding the fusion protein. The fusion protein can be chemically synthesized. The compositions of invention VI are patentably distinct from the composition of invention VII as a nucleic acid encoding a fusion protein are materially different structural, chemical, and functional properties, are made using different reagents and techniques, and are used in different methods. Therefore, the search for each is not co-extensive and it would place an undue burden on the examiner to search and examine both of these inventions together.

7) Inventions VII -IX are patentably distinct in that each of the products is materially different in structural, chemical, and functional properties, is made using different reagents and techniques, and can be used in different methods. Therefore, the search for each is not co-extensive and it would place an undue burden on the examiner to search and examine both of these inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER